

Certificate of Analysis – Certified Reference Material

Certipur® Sodium carbonate

Producer: Merck KGaA, Frankfurter Str. 250, 64293 Darmstadt, Germany
Product no.: 1.02405.0080
Lot no.: 242405X
Description of CRM: Sodium carbonate
Expiry date: 2029/09/30
Storage: +15°C to +25°C tightly closed in the original container and protect from light and moisture
Composition: Sodium carbonate

Analyte	Certified value as mass fraction	Associated uncertainty, $U=k \cdot u$ ($k=2$) as mass fraction
Mass fraction	99.92 %	±0.12 %

Metrological traceability: Directly traceable to the suitable primary standard NIST SRM Tris(hydroxymethyl)-aminomethane 723e.

Measurement method: The certified mass fraction was determined by potentiometric titration with hydro-chloric acid as titration solution. The certified value is based on a molecular mass $M = 105.988$ g/mol dried substance.

Intended use: This volumetric standard is intended for standardisation of volumetric solutions in accordance to the chapter reagents of the Pharmacopoeia.

Instructions for handling and correct use: The volumetric standard Sodium carbonate must be dried at 300 °C for 2 hours before use.
By within-unit homogeneity studies a minimum weigh-in quantity of 100 mg was determined.

Accreditation: Merck KGaA, Darmstadt, Germany is accredited by the German accreditation authority DAkkS as registered reference material producer D-RM-15185-01-00 in accordance with ISO 17034.

Certificate issue date: 2025/01/31



ISO 17034



Deutsche
Akkreditierungsstelle
D-RM-15185-01-00

CRM released by Approving Officer
or delegate of Quality Control

Dipl.-Ing. Ayfer Yildirim
Responsible Laboratory Manager



Health and safety information:

Please refer to the Safety Data Sheet for detailed information about the nature of any hazard and appropriate precautions to be taken.

Certification process details:

Certipur® Volumetric standards are prepared from high purity salts. Characterisation of Certipur® Volumetric standards is carried out by the accredited quality control (QC) laboratory at Merck KGaA, Darmstadt, Germany according to DIN EN ISO / IEC 17025 by measuring the mass fraction by potentiometric titration.

Homogeneity and stability studies are performed with the material according to the requirements of ISO 17034 and ISO Guide 35.

Associated uncertainty:

The associated uncertainty U_{CRM} reported with the certified values is calculated as combined expanded uncertainty $U_{CRM}=k \cdot u_{CRM}$ in accordance with GUM and EA-4/02, with $k=2$ as the coverage factor for a 95% coverage probability.

The combined uncertainty u_{CRM} is derived from combination of the squared uncertainty contributions:

$$u_{CRM} = \sqrt{u^2_{\text{Characterisation}} + u^2_{\text{Homogeneity}} + u^2_{\text{Stability}}}$$

$u_{\text{characterisation}}$:

is the uncertainty in accordance with DIN EN ISO/IEC 17025 which includes the contributions of the primary reference material and the measuring system. The characterisation measurements have been conducted by our DAkkS accredited calibration laboratory.

$u_{\text{homogeneity}}$:

is the between-bottle variation in accordance with ISO 17034. The assessment of homogeneity is performed by analysis of a representative number of systematically chosen sample units.

$u_{\text{stability}}$:

is the uncertainty obtained from short-term and long-term stability in accordance with ISO 17034. The stability studies are the basis for the quantification of the expiry date of this reference material for the unopened bottle.

For more detailed information please read the certification report on our website.

Certificate of analysis revision history:

Certificate version	Date	Reason for version
01	2025/01/31	Initial version

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